

CLAIMS

1

2 What is claimed is:

Sub B1

1. A method of enhancing the immunogenicity of a preselected antigen in a mammal, the method comprising:
  - administering to the mammal intramuscularly, intravenously, transdermally or subcutaneously, a fusion protein comprising an immunoglobulin heavy chain constant region linked by a polypeptide bond to the preselected antigen thereby to elicit an immune response against the preselected antigen, wherein the preselected antigen in the fusion protein elicits a stronger immune response in the mammal than the preselected antigen alone.
2. The method of claim 1, further comprising administering the fusion protein in combination with an adjuvant in an amount sufficient to enhance the immune response against the preselected antigen of the fusion protein relative to the immune response against the preselected antigen of the fusion protein administered without the adjuvant.
3. The method of claim 2, wherein the fusion protein and adjuvant are administered simultaneously.
4. The method of claim 2, wherein the adjuvant comprises a fusion protein comprising an immunoglobulin heavy chain constant region linked by a polypeptide bond to an adjuvant protein.
5. The method of claim 1 or 4, wherein the immunoglobulin heavy chain constant region comprises an immunoglobulin hinge region.
6. The method of claim 5, wherein the immunoglobulin heavy chain constant region comprises an immunoglobulin heavy chain constant region domain selected from the group consisting of a CH2 domain, a CH3 domain, and a CH4 domain.
7. The method of claim 5, wherein the immunoglobulin heavy chain constant region comprises a CH2 domain and a CH3 domain.

1 8. The method of claim 1 or 4, wherein the immunoglobulin heavy chain constant  
2 region is defined by an amino acid sequence corresponding to an amino acid sequence  
3 defining an immunoglobulin heavy chain constant region present in the same species as  
4 the mammal.

1 9. The method of claim 8, wherein the amino acid sequence defining the  
2 immunoglobulin heavy chain constant region corresponds to a human immunoglobulin  
3 heavy chain constant region.

1 10. The method of claim 1, wherein the preselected antigen is selected from the group  
2 consisting of a prostate-specific membrane antigen, an ectodomain of a cytokine receptor,  
3 a viral protein and a tumor-specific protein.

1 11. The method of claim 4, wherein the adjuvant protein is a cytokine.

1 12. The method of claim 11, wherein the cytokine is defined by an amino acid  
2 sequence corresponding to an amino acid sequence defining a cytokine present in the  
3 same species as the mammal.

1 13. The method of claim 12, wherein the cytokine is a human cytokine.

1 14. The method of claim 1, wherein the mammal is a human.

✓ 15. A composition for eliciting an immune response against a preselected antigen in a  
2 mammal, the composition comprising an admixture for intramuscular, intravenous,  
3 transdermal or subcutaneous administration selected from the group consisting of:

4 (a) an antigen fusion protein comprising an immunoglobulin heavy chain  
5 constant region linked by a polypeptide bond to the preselected antigen admixed with an  
6 adjuvant; and

7 (b) a preselected antigen admixed with an adjuvant fusion protein comprising  
8 an immunoglobulin heavy chain constant region linked by a polypeptide bond to an  
9 adjuvant protein.

- 1 16. The composition of claim 15, wherein the adjuvant of clause (a) comprises a  
2 fusion protein comprising an immunoglobulin constant region linked by a polypeptide  
3 bond to an adjuvant protein.
- 1 17. The composition of claim 15, wherein the preselected antigen of clause (b) is  
2 linked by a polypeptide bond to an immunoglobulin heavy chain constant region.
- sub 83 18. The composition of claim 15, 16 or 17, wherein the immunoglobulin heavy chain  
2 constant region comprises an immunoglobulin hinge region.
- 1 19. The composition of claim 18, wherein the immunoglobulin heavy chain constant  
2 region comprises an immunoglobulin heavy chain constant region domain selected from  
3 the group consisting of a CH2 domain, a CH3 domain, and a CH4 domain.
- 1 20. The composition of claim 18, wherein the immunoglobulin heavy chain constant  
2 region comprises a CH2 domain and a CH3 domain.
- 1 21. The composition of claim 15, wherein the adjuvant of clause (a) comprises an  
2 oligonucleotide CpG sequence.
- 1 22. The composition of claim 15, wherein the preselected antigen is selected from the  
2 group consisting of a prostate-specific membrane antigen, an ectodomain of a cytokine  
3 receptor, a viral protein and a tumor-specific protein.
- 1 23. The composition of claim 15, wherein the antigen fusion protein of clause (a) or  
2 the adjuvant fusion of clause (b) is linked by a disulfide bond to a second  
3 immunoglobulin heavy chain constant region.
- 1 24. The composition of claim 15, wherein the adjuvant of clause (a) or the adjuvant  
2 protein of clause (b) is a cytokine.
- 1 25. The composition of claim 24, wherein the cytokine is a human cytokine.
- sub 84 26. The composition of claim 15, 16 or 17, wherein the immunoglobulin heavy chain  
2 constant region is defined by a amino acid sequence corresponding to an amino acid  
3 sequence defining a human immunoglobulin heavy chain constant region.

✓ 1 27. A method of enhancing the immunogenicity of a preselected antigen in a  
2 mammal, the method comprising:

3 administering to the mammal a nucleic acid sequence encoding a fusion protein  
4 comprising an immunoglobulin heavy chain constant region linked to the preselected  
5 antigen, whereupon expression of the nucleic acid sequence in the mammal results in the  
6 production of the fusion protein, the preselected antigen of which elicits a stronger  
7 immune response than the preselected antigen expressed from a nucleic acid encoding the  
8 preselected antigen alone.

1 28. The method of claim 27, wherein the nucleic acid encodes in a 5' to 3' direction  
2 the immunoglobulin heavy chain constant region and the preselected antigen.

1 29. The method of claim 28, wherein the immunoglobulin heavy chain constant  
2 region comprises an immunoglobulin hinge region.

30. The method of claim 27 or 29, wherein the immunoglobulin heavy chain constant  
region comprises a heavy chain domain selected from the group consisting of a CH2  
domain, a CH3 domain, and a CH4 domain.

31. The method of claim 29, wherein the immunoglobulin heavy chain constant  
region comprises a CH2 domain and a CH3 domain.

32. The method of claim 27, wherein the preselected antigen is selected from the  
group consisting of a prostate-specific membrane antigen, an ectodomain of a cytokine  
receptor, a viral protein and an cancer-specific antigen.

1 33. The composition of claim 27, further comprising administering the nucleic acid  
2 sequence in combination with an adjuvant.

1 34. The method of claim 33, wherein the adjuvant comprises a nucleic acid sequence  
2 encoding an fusion protein comprising an immunoglobulin heavy chain constant region  
3 linked to an adjuvant protein.

✓ 1 35. A composition for eliciting an immune response against a preselected antigen in a  
2 mammal, the composition comprising:

3 (a) a first nucleic acid sequence encoding a fusion protein comprising an  
4 immunoglobulin heavy chain constant region and the preselected antigen, whereupon  
5 expression of the nucleic acid sequence in the mammal results in production of the fusion  
6 protein, the preselected antigen of which elicits a stronger immune response than the  
7 preselected antigen expressed from a nucleic acid encoding the preselected antigen alone;  
8 and

9 (b) an adjuvant.

1 36. The composition of claim 35, wherein the adjuvant comprises a second nucleic  
2 acid sequence encoding a fusion protein comprising an immunoglobulin heavy chain  
3 constant region linked by a peptide bond to an adjuvant protein.

4 37. The composition of claim 35 or 36, wherein the immunoglobulin heavy chain  
5 constant region comprises an immunoglobulin hinge region.

6 38. The composition of claim 35 or 36, wherein the immunoglobulin heavy chain  
7 constant comprises an immunoglobulin heavy chain domain selected from the group  
8 consisting of a CH2 domain, a CH3 domain, and a CH4 domain.

9 39. The composition of claim 37, wherein the immunoglobulin heavy chain constant  
1 comprises an immunoglobulin heavy chain domain selected from the group consisting of  
2 a CH2 domain, a CH3 domain, and a CH4 domain.

3 40. The composition of claim 35, wherein the preselected antigen is selected from the  
4 group consisting of a prostate-specific membrane antigen, an ectodomain of a cytokine  
5 receptor, a viral protein and a cancer-specific antigen.

6 41. The composition of claim 36, wherein the adjuvant protein is a cytokine.

7 42. The composition of claim 35, wherein the first nucleic acid sequence is operably  
8 disposed within a replicable expression vector.

1 43. The composition of claim 36, wherein the second nucleic acid sequence is  
2 operably disposed within a replicable expression vector.

✓ 1 44. A method for enhancing the immunogenicity of a preselected antigen in a  
2 mammal, the method comprising:

3 administering to a mammal, either simultaneously or sequentially, a first fusion  
SUB A1 4 protein comprising an antigen protein with a localizing protein, and a second fusion  
5 protein comprising an adjuvant protein and said localizing protein, said localizing protein  
6 causing an increase in concentration of said first and second fusion proteins in a region of  
7 the mammal accessible to the immune system.

✓ 1 45. A method for enhancing the immunogenicity of a preselected antigen in a  
2 mammal, the method comprising:

3 administering to a mammal a fusion protein comprising an antigen protein, an  
4 adjuvant protein and a localizing protein, said localizing protein causing an increase in  
5 concentration of said antigen and adjuvant proteins in a region of the mammal accessible  
6 to the immune system.

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